

DOCKET NO: 263361US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
ANDREA CAPOCCHI : EXAMINER: M.C. HENRY
SERIAL NO: 10/516,945 :
FILED: AUGUST 23, 2005 : GROUP ART UNIT: 1623
FOR: A PROCESS FOR THE PREPARATION OF PIROXICAM: B-CYCLODEXTRIN
INCLUSION COMPOUNDS

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VA 22313-1450

SIR:

Now comes DANIELA BRIGHENTI who
deposes and states that:

1. I am qualified CHEMIST and received
my Diploma in the year 1987.
2. I have been employed by CHIESI FARMACEUTICI
for 20 years as a LABORATORY
TECHNICIAN in the field of ANALYTICAL CHEMISTRY.
3. I have read and am familiar with U.S. patent application serial No. 10/516,945.
4. I have read and am familiar with the contents of the Office Action dated October 20, 2008 in U.S. patent application serial No. 10/516,945. I have also read and understand Chiesi et al., European Patent No. 0 153 998 A2 cited in that Office Action.

5. The following experiments were carried out by me or under my direct supervision and control.

20 grams of 1:2.5 piroxicam: β -cyclodextrin obtained according to the method of the present invention, corresponding to about 2.1 grams of piroxicam, were put in a dissolution test apparatus Sotax A76, and then 250 ml of water were introduced. Then, the resulting dispersion was maintained under stirring at 125 r.p.m. After 15 minutes, an aliquot of the solution was withdrawn and filtered. The amount of dissolved piroxicam, measured by UV spectrophotometry, turned out to be 0.5 g/100 ml.

Under similar conditions, using 7.5 grams of 1:2.5 piroxicam: β -cyclodextrin, corresponding to 0.78 grams of piroxicam, the lyophilized product of Chiesi et al. gave rise after 30 minutes to an amount of dissolved piroxicam of 0.0453 g/100 ml (see page 5, lines 15-29).

6. These data demonstrate that the dissolution kinetics of the lab scale lyophilized product of Chiesi et al. is slower than that of the lyophilized product of the present invention.

7. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

8. Further deponent saith not.

Diane Brughent
Signature

05/02/2009
Date